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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,743	03/29/2005	Jean-Thierry Simonnet	267329US0PCT	8358

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ALEXANDRIA, VA 22314

EXAMINER

KASSA, TIGABU

ART UNIT	PAPER NUMBER
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1619

NOTIFICATION DATE	DELIVERY MODE
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10/12/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/529,743	Applicant(s) SIMONNET, JEAN-THIERRY	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-52, 54-66, 68-82 and 84-88 is/are pending in the application.
- 4a) Of the above claim(s) 41-52, 54-60, 81, 82 and 86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-66, 68-80, 84, 85, 87 and 88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/08/10 has been entered.

Formal Matters

Applicants' amendments filed on 09/29/2010 are acknowledged and entered due to request for continued examination. **Claims 41-52, 54-66, 68-82, 84-88 are currently pending.** **Claims 61-66, 68-80, 84-85, and 87-88 are under consideration in the instant office action.** Claims 41-52, 54-60, 81-82, and 86 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 1-40, 53, 67, and 83 are cancelled. This Office Action is FINAL.

Updated Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Applicant's claim of foreign priority to FR 0213101 is DENIED because no translation of the French language document has been provided. Benefit is accorded to the filing date of the US provisional application 60/432619, filed on 12/12/02.

Rejections Maintained***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 61-66, 68-73, 75-80, 84, and 87-88 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) in view of L'Alloret (US Patent No. 6994846), for the reasons of record and the reasons set forth herein.

Response to arguments

Applicants' arguments filed on 09/29/2010 have been fully considered but they are not persuasive.

Applicant asserts that in accordance with the discussion at the Interview, claim 61 has been amended to require the presence of at least one block amphiphilic copolymer in which the lipophilic compound is solubilized, wherein the amphiphilic copolymer forms micelles on contact

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with water. The present invention relates to compositions comprising at least one block amphiphilic copolymer in which the lipophilic compound is solubilized, wherein the amphiphilic copolymer forms micelles on contact with water - that is, no need exists for first solubilizing the lipophilic compound in a solvent as well as a polymer, and then forming micelles by contacting the mixture with water. Rather, the present invention relates to combining the lipophilic compound and the required compound to solubilize the lipophilic compound in the required polymer (regardless of whether solvent is also present), and then contacting the lipophilic compound/required polymer mixture with water to form micelles. Stated another way, the present invention relates to new ways to solubilize a lipophilic using the unique polymers of the present invention. None of the applied art teaches or suggests this invention. . Applicant argues that Seo discloses dissolving a polymer in a solvent (PEG, optionally including other organic solvents), and dissolving a drug in the polymer/PEG mixture. Thus, Seo teaches dissolving a drug in PEG - PEG is a vital, necessary component of Seo's dissolution mixtures. PEG also plays a vital role in forming micelles in Seo. Thus, Seo does not teach or suggest solubilizing a lipophilic compound in a solubilizing effective amount of at least one block amphiphilic copolymer and/or forming micelles by contacting the polymer with a solvent consisting essentially of water as required by present independent claim 61.

This is not found persuasive because applicant's amendment incorporating the limitation reciting the presence of at least one block amphiphilic copolymer "in which the lipophilic compound is solubilized," wherein the amphiphilic copolymer forms micelles on contact with water do not overcome the rejection of record because of the reasons set forth in the previous office action which are also delineated as set forth below. The examiner respectfully disagrees with these assertions because applicant in the claim recitation uses the transitional phrase "comprising". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or **open-ended and does not exclude**

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additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) (“like the term comprising,’ the term containing’ and mixture’ are open-ended.”). The incorporation of poly ethylene glycol or any other solvents is not excluded in the cosmetic composition. With regard to the limitation that amphiphilic copolymer forms micelles on contact with water, the examiner contends that to the minimum Seo et al., teach a composition capable of forming a micelle in body fluids or in **aqueous medium** (see abstract, page 5). As clearly described above Seo et al. teach that the micelles can be formed in aqueous environment. Furthermore, although the claims are examined in light of the specification, applicant's examples in the original specification disclose compositions wherein the block copolymer is dissolved in **dichloromethane** which is organic solvent with excess DHEA (lipophilic compound) (see page 18 example 1); the block copolymer is dissolved in **dichloromethane** which is organic solvent with excess Parsol® 1789(lipophilic compound) (page 18 example 2); and in the oil phase vitamin E (lipophilic compound) is incorporated in the composition containing liquid petroleum jelly and petroleum jelly which are organic solvents (see pages 21-22 examples 3-4) contrary to applicant's assertions.

Applicant also argues that Seo does not even teach or suggest the claimed polymers. Because Seo does not teach or suggest the required polymers, it necessarily cannot teach or suggest combining a lipophilic compound with such a non-disclosed polymer, or any benefits associated with such a hypothetical combination such as, for example, solubilization of the lipophilic compound in the non-disclosed block amphiphilic copolymer.

This is not found persuasive because Seo et al., clearly teach a composition comprising **a block copolymer containing a hydrophilic and a hydrophobic polymer block** (abstract). The composition comprises an amphiphilic block copolymer has a hydrophilic poly(alkylene glycol), which is a nonionic polymer and a hydrophobic biodegradable polymer component (abstract). Preferred **hydrophobic polymer may be, e.g., polycaprolactone (page 6)**. The amphiphilic

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block copolymer as described through out the document does not comprise an ionic water-soluble polymer block. The amphiphilic polymer **solubilizes poorly water soluble drugs (i.e. lipophilic compounds) in aqueous media** (abstract). The examiner acknowledges that Seo et al. do not teach the specific hydrophobic polymers recited in instant claims 61, 66, 68 and 69, nor of the amphiphilic polymers taught in instant claim 71. However, these deficiencies are cured as clearly described above by the teachings of L'Alloret.

Applicant argues that L'Alloret requires the presence of an ionic water-soluble hydrophilic polymer block that results in synergistic gellation which is in contrast to the polymers of Seo which have nonionic hydrophilic blocks and hydrophobic blocks which form micelles.

This is not found persuasive because the polymers disclosed by Seo et al., and the polymers disclosed by L'Alloret are both amphipathic polymers and both types of polymers therefore would be expected to be capable of forming micelles. Both polymers would also be expected increase the viscosity of the compositions to which they are added; in other words to gel the composition.

Applicant argues that since different results are expected based on the teachings of the two references, there is no motivation to combine the references with the expectation that a suitable product would result.

This is not found persuasive because both amphipathic polymers would be expected to be capable of forming micelles exactly because they are amphipathic. In the absence of surprising and/or unexpected results, substitution of one amphipathic polymer for another is prima facie obvious.

Applicants argue that given the vastly different products of the two references nothing would have lead one of ordinary skill in the art to substitute the blocks taught by one reference for the blocks taught by the other reference.

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This is not found persuasive because the compositions of Seo et al., and L'Alloret are not vastly different; they are both compositions suitable for topical administration of active agents (Seo, page 9, last paragraph and L'Alloret abstract and column 17, lines 29-50).

Applicant has not demonstrated how the claimed product is patentably distinct from the cited prior art nor do the claims as currently written distinguish the instant invention over the prior arts. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

This office action is FINAL.

All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne P. Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

9/30/10

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647